**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MARYLAND**

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| **KERALINK INT'L, INC.** | * | |
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| **Plaintiff** | * | |
| | * | |
| **v.** | * | |
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| **STRADIS HEALTHCARE, LLC and GERI-CARE PHARMACEUTICALS CORP.** | * | |
| | * | |
| **Defendants** | * | **Civil Action No. CCB-18-2013** |
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| **STRADIS HEALTHCARE, LLC** | * | |
| | * | |
| **Third Party Plaintiff** | * | |
| | * | |
| **v.** | * | |
| | * | |
| **INSOURCE, INC. and GERI-CARE PHARMACEUTICALS CORP.** | * | |
| **Third Party Defendants** | * | |

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**MEMORANDUM**

Pending before the court in this products-liability action are Geri-Care Pharmaceuticals Corporation ("Geri-Care")'s motion for summary judgment against Stradis Healthcare, LLC ("Stradis") (ECF No. 117), its motion for summary judgment against KeraLink International, Inc. ("KeraLink") (ECF No. 118), and its motion in limine to exclude certain damages claimed by Stradis (ECF No. 129); KeraLink's motion for summary judgment against Stradis and Geri-Care (ECF No. 123); Stradis's motions for summary judgment against KeraLink (ECF No. 127), Geri-Care (ECF No. 128), and InSource, Inc. ("InSource") (ECF No. 132); and InSource's motion for

summary judgment against Stradis (ECF No. 122).[1] The motions are fully briefed, and no oral argument is necessary. *See* Local Rule 105.6 (D. Md. 2021). For the reasons that follow, the court will grant in part and deny in part Geri-Care's motions for summary judgment, KeraLink's motion for summary judgment, and Stradis's motion for summary judgment against Geri-Care; deny Stradis's motions against KeraLink and InSource; grant InSource's motion; and deny Geri-Care's motion in limine.

## BACKGROUND

This litigation arises from the inclusion of contaminated sterile eye wash ("Geri-Care Eye Wash" or "eyewash"), in surgical packs used to recover corneal tissue. KeraLink, a national network of eye banks that recovers and distributes ocular tissue for use in corneal implants, purchased these surgical packs from Stradis. After the Eye Bank Association of America ("EBAA") in 2017 notified its members that batches of Geri-Care Eye Wash may be contaminated, KeraLink quarantined, and eventually could not use, some ocular tissue that had been recovered using Geri-Care Eye Wash, resulting in monetary damages.

KeraLink is a not-for-profit charitable corporation with its headquarters and principal place of business located in Baltimore, Maryland. (ECF No. 123-26, Buckley Aff. ¶ 6). During the relevant time period, KeraLink was a network of eye banks located throughout the United States, including in Maryland, Florida, Massachusetts, Texas, New Mexico, and California. (*Id.* ¶ 7). These eye banks recover corneas and other ocular tissue from recently deceased human donors for

[1] Also pending are several discovery-related motions brought by Geri-Care, including its motion for an order to show cause why Corneagen, Inc. should not be held in contempt for failure to respond to a third-party subpoena (ECF No. 110), and its motions to compel certain discovery responses from KeraLink and Stradis (ECF Nos. 107, 109). The discovery sought in these motions is not necessary to resolve the motions for summary judgment. Therefore, they will be denied as moot.

transplantation into living patients. (*Id.* ¶ 8). To recover tissue, KeraLink uses a sterile surgical pack which is specifically designed to contain everything needed to perform the procedure. (*Id.* ¶ 10).

KeraLink purchased some sterile surgical packs, or "Custom Stradi-Paks" from Stradis. (*Id.* ¶ 11). KeraLink ordered the Custom Stradi-Paks from Stradis pursuant to purchase orders initiated in Baltimore which were then signed by Stradis and sent back to KeraLink in Baltimore where they were counter signed. (ECF No. 118-5, Sokol Dep. at 59–60, 149; ECF No. 123-26, Buckley ¶¶31–32). The Custom Stradi-Paks were then shipped to KeraLink, largely in Maryland though occasionally, at KeraLink's direction, to KeraLink operations in other states. (ECF No. 123-26, Buckley Aff. ¶ 33).

Stradis markets itself as a "supporter of cornea and tissue banks," stating, "Our expertise in eye banking and corneal transplantation make us an ideal partner for implementing medical standards to your eye bank operations and procedures. Our custom trays are designed to help recover the highest quality tissue in the most efficient way possible." (ECF No. 123-35 at 2). Stradis's principal place of business is in Georgia, and it packaged and assembled the Stradi-Paks there. (ECF No. 118-5, A. Sokol Dep. at 15, 24). Stradis determines the contents of each surgical pack based on the customer's individual requests, which can be generic or by brand. (*Id.* at 17–18, 61, 151). KeraLink did not specify in its requests that it wanted a particular brand of eyewash. (*Id.* at 149). Stradis stocked the Custom-Stradi Paks for KeraLink to include one bottle of Geri-Care Eye Wash ("the eyewash"). (ECF No. 123-26, Buckley Aff. ¶ 12). The Stradi-Paks included an

inventory of contents that listed the eyewash as "STERILE EYE WASH." (ECF No. 123-33; ECF No. 127-6).[2]

The eyewash found its way into the Custom-Stradi-Paks through several other businesses. Defendant Geri-Care purchased the eyewash from Kareway Product, Inc. ("Kareway"), a California company which had obtained the eyewash from the manufacturer, a company in Korea. (ECF No. 118-6, Kleyn Dep. at 91). Geri-Care wanted to begin selling a private label eyewash in order to have Geri-Care's name on the market. (*Id.* at 18). Its agreement with Kareway was that Kareway would provide a private-label eyewash to Geri-Care, carrying the Geri-Care logo and brand, that was comparable to Bausch & Lomb Advanced Eye Care. (*Id.* at 78).[3] Geri-Care specified that the eyewash was to be comparable to that product, with a label that was reminiscent of that product. (*Id.* at 78–79). Though the eyewash was an existing product of Kareway's, the agreement between Kareway and Geri-Care made Geri-Care the exclusive seller of the eyewash, including to other companies that wanted their own private label on the same eyewash. (*Id.* at 29–30, 35).

Geri-Care provided a logo and distribution statement to Kareway to place on the eyewash bottles and was able to review and make changes to the label. (ECF No. 118-6, Kleyn Dep. at 19–20; ECF No. 123-8 at 5). It reviewed the label and box for "accuracy," (ECF No. 118-6, Kleyn Dep. at 20) and directed Kareway to make a number of changes to the label, including edits to the directions for use, changing the expiration date, and inserting comparisons to Bausch & Lomb eyewash. (ECF No. 123-9; ECF No. 118-6 at 11–14). Geri-Care specified to Kareway that the

[2] The "sterile eye wash" was listed on the inventory under the heading "non-sterile components" to indicate that the outside of the bottle itself may not have been sterile. (ECF No. 118-5, Sokol Depo. at 157). The contents of the eyewash bottle were meant to be sterile, and Stradis represented that the contents were sterile. (*Id.* at 157–58).

[3] Geri-Care never communicated with the Korean company. (*Id.* at 91–92).

eyewash should be sterile. (ECF No. 118-6, Kleyn Dep. at 80). The label indicates that the eyewash is a "STERILE EYE IRRIGATING SOLUTION," that it is "Distributed by Geri-Care Pharmaceuticals Corp.," and that it is a "Product of Korea." (ECF No. 123-5; ECF No. 123-9; ECF No. 123-8 at 3, 4, 5).

Geri-Care's corporate representative has stated that the company was aware that customers expected the eyewash to be sterile. (ECF No. 118-6, Kleyn Dep. at 26). It was important to Geri-Care that the product was safe, and it wanted to make sure that the product did not harm the eyes or the vision of any customer. (*Id.* at 27). Geri-Care recognized that it had to be "super cautious" when selling a sterile product intended for the eyes because of the danger that the eyewash could become contaminated. (*Id.* at 25).

Geri-Care marketed the eyewash to the public as a Geri-Care product, and Geri-Care's corporate representative testified that the company wanted the public to think it was the manufacturer of the product. (*Id.* at 76, 114). The label does not indicate what company manufactured the product in Korea. (*Id.* at 76). Geri-Care is the only company named on the label. (*Id.* at 77). There was no way for a purchaser of the eyewash to know that Geri-Care was not the manufacturer and did not have facilities in Korea. (*Id.* at 113). The publicly available FDA registration for the eyewash identifies Geri-Care as the registrant and the labeler. (ECF No. 123-4; ECF No. 123-6).

Geri-Care received the eyewash, packaged, sealed, and labeled, from Kareway. (ECF No. 118-6, Kleyn Dep. at 8). The eyewash was delivered in large boxes, each of which contained approximately twenty-four sealed units of eyewash. (ECF No. 118-9, Kleyn Aff. ¶ 3–5). Geri-Care did not open the boxes and did not conduct any testing to confirm the sterility of the eyewash prior to distributing the product. (ECF No. 118-9, Kleyn Aff. ¶ 6; ECF No. 118-6, Kleyn Dep. at 103).

Instead, Geri-Care relied on a certificate of analysis from Kareway that accompanied each box of eyewash, which included the lot number, the contents, and whether the product had been tested. (ECF No. 118-9, Kleyn Dep. at 23, 100).

Geri-Care shipped some of the eyewash, including at least part of Lot #86041601, in its original packaging, to Henry Schein, Inc., an affiliate of InSource, Inc. (ECF No. 118-9, Kleyn Aff. ¶ 6; ECF No. 122-4 at 5–7). InSource is a wholesaler that fills orders from customers for an assortment of products. (ECF No. 122-4 at 19). InSource received the eyewash from Geri-Care prepackaged and did not alter, change, or repackage the product in any way. (ECF No. 122-4 at 7). InSource then sold the eyewash to Stradis. (ECF No. 118-5, Sokol Dep. at 43). Stradis received the eyewash from Insource at Stradis's Georgia facilities. (*Id.* at 138). Stradis's packaging process is regulated by the FDA, and it assembles the Custom-Stradi-Paks according to Stradis's Standard Operating Procedures and FDA regulations. (*Id.* at 26, 34, 49). This process consisted of removing the bottles of eyewash from their original packaging and inspecting them to ensure they had a plastic heat seal on the opening cap and a lot number. (*Id.* at 142–43). The bottles of eyewash were then repackaged, along with other components, into Stradi-Paks. This was done in an assembly room with a "positive pressure . . . so that there's no contaminates in the room." (*Id.* at 55–56). Stradis did not conduct any testing to confirm the sterility of the eyewash before packaging it into Custom-Stradi-Paks; rather, it relied on the representation on the label that the eyewash was sterile. (*Id.* at 105, 157–58). Stradis labeled each Stradi-Pak as "Sterile: Unless Opened or Damaged" and stated that the Stradi-Pak was "Manufactured & Distributed by Stradis Healthcare, LLC." (ECF No. 123-31; ECF No. 123-33).

KeraLink used the eyewash in procedures for the recovery, handling, and processing of corneal and other ocular tissue. (ECF No. 123-26, Buckley Aff. ¶ 12). These procedures are

governed by FDA regulations and EBAA standards. (*Id.*). The eyewash was used, in accordance with those regulations and standards, to prepare the tissue initially by irrigating it to remove particulates and other foreign bodies, and again after the tissue was treated with an antiseptic solution to re-irrigate the tissue. (*Id.*).

On August 29, 2017, Geri-Care received a report from a customer, the San Diego Eye Bank (not affiliated with KeraLink), that eyewash in lot No. 86041601 was contaminated. (ECF No. 123-10). The San Diego Eye Bank sent the bottles back to Geri-Care, and Geri-Care then forwarded the bottles to Kareway for investigation. Kareway concluded that "the product meets all of its specifications" and the product was sterile. (*Id.*; ECF No. 123-20; ECF No. 133-3). On October 27, 2017, Stradis notified Geri-Care that one of its customers, the Alabama Eye Bank (also not affiliated with KeraLink) used eyewash from lot No. 86041601 to perform its procedures and had "a few patients who contracted bacterial infection." (ECF No. 123-12). The Alabama Eye Bank had an unopened bottle of the eyewash tested by a third party; testing indicated that the eyewash was positive for *Achromobacter xylosoxidans*.[4] Geri-Care instructed Stradis to quarantine all eyewash in its possession and to have its customers do the same. Geri-Care further asked that Stradis send to Geri-Care a dozen bottles of the eyewash. (ECF No. 123-13 at 3–4). On the same day, Geri-Care asked InSource/Henry Schein to quarantine all eyewash in lot No. 86041601. (ECF No. 123-15).

On November 2, 2017, Geri-Care sent a request to Microconsult, Inc. to test eyewash from lot No. 86041601. (ECF No. 123-18 at 10). Testing results from November 5, 2017, identified that

[4] The notification from Stradis to Geri-Care uses the name "*alcaligenes xylosxidans*" to identify the bacteria in question. The parties use that name interchangeably with *Achromobacter xylosoxidans* and do not dispute that they are the same bacteria. The court will use *Achromobacter xylosoxidans* to identify the bacteria.

samples of the eyewash tested positive for *Achromobacter xylosoxidans*. (*Id.* at 10–16). Geri-Care's corporate representative has stated that she did not believe nor rely on Kareway's initial testing that indicated the eyewash was sterile once Geri-Care received these results. (ECF No. 118-6, Kleyn Dep. at 90).

KeraLink learned of the potential contamination when, on October 27, 2017, the EBAA distributed a notification that it had received a report from a member eyebank regarding the potentially contaminated eyewash. (ECF No. 123-36; ECF No. 123-26, Buckley Aff. ¶ 14; ECF No. 124). The notification indicated *Achromobacter xylosoxidans* "causes opportunistic infections and is a common contaminant" but "no adverse reactions [had] been reported to date." (ECF No. 123-36). In response to the notification, KeraLink's VP of Ocular operations, Thomas Buckley, coordinated an investigation into KeraLink's purchase and use of the eyewash in order to determine the appropriate remedial measures and identify any financial or other impacts on KeraLink. (ECF No. 123-26, Buckley Aff. ¶ 15). On November 2, 2017, KeraLink instructed all KeraLink directors and management to immediately: (A) identify and quarantine all corneas recovered using eyewash from lot No. 86041601; (B) identify and quarantine all corneas recovered using any Stradi-Paks except those that could be certified that the eyewash was not contained within them; (C) identify and quarantine all Stradi-Paks containing the eyewash; (D) compile a list of all quarantined corneas and Stradi-Paks; and (E) begin using a replacement eyewash. (*Id.* ¶ 17). KeraLink has identified corneas in five patients who received transplants of corneal tissue recovered using the eyewash that were positive for a culture closely related to, if not the same as, the one identified in the eyewash. (ECF No. 124 at 7; ECF No. 123-38 at 4, 5). At the time KeraLink was informed of the cultures, none of the patients had any signs of clinical infection. (ECF No. 123-38 at 4, 5). KeraLink itself hired an independent laboratory to test the eyewash.

That testing revealed that eight out of ten tested bottles were positive for the presence of *Achromobacter xylosoxidans*. (ECF No. 125 at 108; ECF No. 124 at 6–7).

On November 13, 2017, Kareway issued a voluntary recall of the eyewash titled "URGENT: DRUG RECALL." The recall states that it was "initiated due to complaints received on [sic] potential product contamination which compromises sterility. Use of contaminated product has a potential to result in infection that may be sight-threatening." (ECF No. 124 at 16). Kareway published a similar voluntary recall notice with the FDA in January 2018. That notice included the following "risk statement:" "The product potentially could be calamitous for any population due to a probability of a potentially sight threatening eye infection or impairment. Kareway Products, Inc has not received any reports of adverse events related to this recall." (ECF No. 123-25 at 3). KeraLink has included in the record three peer-reviewed articles that discuss the danger to eye patients posed by *Achromobacter xylosoxidans*. (ECF No. 123-27; ECF No. 123-28; ECF No. 123-26, Ex. A to Buckley Aff.).

Under FDA regulations, an establishment that recovers human cells, tissues, or cellular or tissue-based products ("HCT/Ps"), including corneas, "must recover each HCT/P in a way that does not cause contamination or cross-contamination during recovery, or otherwise increase the risk of the introduction, transmission, or spread of communicable disease through the use of the HCT/P." 21 C.F.R. §§ 1271.215 (recovery of HCT/Ps), 1271.3(d) (defining HCT/Ps), 1271.3(r) (defining "relevant communicable disease agent or disease").[5] There is no dispute that under these

[5] A "relevant communicable disease agent or disease" is defined as, *inter alia*, "a disease agent or disease . . . for which there may be a risk of transmission by an HCT/P or to the recipient of the HCT/P . . . because . . . the disease agent or disease may have been released accidentally or intentionally in a manner that could place potential donors at risk of infection [] that could be fatal or life-threatening, could result in permanent impairment of a body function or permanent damage to body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of body function or permanent damage to a body structure . . . [.]" *Id.*

regulations, KeraLink could not use any tissue exposed to the eyewash. KeraLink has identified Mr. Buckley as a hybrid fact/expert witness in this case who is expected to testify "as to the procedures for the recovery, handling, and processing corneal tissue for transplant" governed by the FDA and the EBAA, and "ocular recovery and transplant methodologies, principles, practices, and the need for sterile eye wash during recovery[.]" (ECF No. 123-29 at 5–6).

KeraLink initiated this action in July 2018 and, a month later, Stradis filed a third-party complaint against InSource and Geri-Care, seeking indemnification and contribution. (ECF No. 1; ECF No. 10).[6] KeraLink has since amended its complaint (ECF No. 75) and brings claims of strict liability and breach of express and implied warranty against Stradis and Geri-Care and a negligence claim against Geri-Care. Stradis also has amended its third-party complaint to include strict liability and breach of express and implied warranty claims against Geri-Care. (ECF No. 84). Discovery in this case closed in September 2020, following the Rule 30(b)(6) depositions of Geri-Care and Stradis. (ECF No. 104; ECF No. 118-5; ECF No. 118-6). Geri-Care, Stradis, and KeraLink each have filed cross motions for summary judgment, and Stradis and InSource also have filed cross motions for summary judgment. (ECF Nos. 117, 118, 122, 123, 127, 128, 132). Geri-Care also has moved *in limine* to exclude certain of Stradis's damages. (ECF No. 129). These motions are ripe and ready for resolution.

## DISCUSSION

### I. Standard of Review

Federal Rule of Civil Procedure 56(a) provides that summary judgment should be granted "if the movant shows that there is no *genuine* dispute as to any *material* fact and the movant is

[6] Stradis's complaint also named Kareway as a defendant. The court has dismissed the third-party complaint as to Kareway for lack of personal jurisdiction, (ECF Nos. 35, 36) and Kareway is no longer a party to this case.

entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a) (emphases added). "A dispute is genuine if 'a reasonable jury could return a verdict for the nonmoving party.'" *Libertarian Party of Va. v. Judd*, 718 F.3d 308, 313 (4th Cir. 2013) (quoting *Dulaney v. Packaging Corp. of Am.*, 673 F.3d 323, 330 (4th Cir. 2012)). "A fact is material if it 'might affect the outcome of the suit under the governing law.'" *Id.* (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). Accordingly, "the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment[.]" *Anderson*, 477 U.S. at 247–48. "When faced with cross-motions for summary judgment, the court must review each motion separately on its own merits 'to determine whether either of the parties deserves judgment as a matter of law.'" *Rossignol v. Voorhaar*, 316 F.3d 516, 523 (4th Cir. 2003) (quoting *Phillip Morris Inc. v. Harshbarger*, 122 F.3d 58, 62 n.4 (1st Cir. 1997). For each individual motion, the court must view the evidence in the light most favorable to the nonmoving party, *Tolan v. Cotton*, 572 U.S. 650, 656 (2014) (per curiam), and draw all reasonable inferences in that party's favor, *Scott v. Harris*, 550 U.S. 372, 378 (2007) (citations omitted); *see also Jacobs v. N.C. Admin. Office of the Courts*, 780 F.3d 562, 568–69 (4th Cir. 2015). At the same time, the court must "prevent factually unsupported claims and defenses from proceeding to trial." *Bouchat v. Balt. Ravens Football Club, Inc.*, 346 F.3d 514, 526 (4th Cir. 2003) (quoting *Drewitt v. Pratt*, 999 F.2d 774, 778–79 (4th Cir. 1993)).

**A. Choice of Law**

Before turning to the merits of the motions, the court must resolve the parties' choice of law dispute. KeraLink, Stradis, and InSource request that the court apply Maryland law to all of the claims in this case. Geri-Care strongly disagrees, and advances the theory that the court should apply the laws of each state in which ocular tissue was allegedly contaminated to resolve KeraLink

and Stradis's tort claims and the laws of Florida (and if not Florida, New York or Georgia) to resolve KeraLink's and Stradis's breach of warranty claims.

**a. Strict Liability, Negligence, and Indemnification and Contribution**

The district court, sitting in diversity, applies the conflict of law rules of the jurisdiction in which it sits; here, Maryland. *See DiFederico v. Marriott Int'l, Inc.*, 714 F.3d 796, 807 (4th Cir. 2013). In actions that lie in tort, Maryland courts apply the principle of *lex loci delicti*, meaning "the applicable law is the law of the 'state where the last event necessary to make an actor liable for an alleged tort takes place.'" *Id.* (quoting *Wells v. Liddy*, 186 F.3d 505, 521 (4th Cir. 1999)). As a general rule, this is considered to be the place of the injury. *Philip Morris, Inc. v. Angeletti*, 358 Md. 689, 745–46 (2000).

Geri-Care argues that there are multiple places of injury in this case—the locations in which each individual contamination of each piece of ocular tissue occurred once the eyewash was used, including California, Connecticut, the District of Columbia, Florida, Maryland, Maine, Massachusetts, New Hampshire, Rhode Island, Texas, Vermont, and Virginia, necessitating the application of each state's law to resolve KeraLink's and Stradis's tort claims. (ECF No. 118-1 at 14). KeraLink contends that Maryland law applies, because it experienced injury in the form of property damage and economic loss in Maryland, where KeraLink is headquartered and has its principal place of business. The court agrees with KeraLink.

KeraLink claims losses associated with its inability to use corneal tissue damaged by the contaminated eyewash, the costs of replacing 182 Stradi-Paks containing the contaminated eyewash, and the costs of diverting personnel resources to responding to the contamination. (ECF No. 123-26, Buckley Aff. ¶ 24–26). These are injuries of property damage and economic loss largely experienced in Maryland, as KeraLink has its headquarters and principal place of business

localed in Baltimore, Maryland. (ECF No. 123-26, Buckley Aff. ¶ 6).[7] This case is similar to *Bank of Louisiana v. Marriott Int'l, Inc.*, 438 F. Supp. 3d 433, 442–43 (D. Md. 2020). In that case, the Bank of Louisiana brought negligence claims against Marriott for economic losses sustained as a result of a data breach to Marriott's database of customer payment card numbers. *Id.* at 437. The parties disagreed as to whether the loss was felt in Maryland, where Marriott's alleged negligent acts in failing to reasonably secure its data occurred, or in Louisiana, where the economic loss was sustained. The court rejected the argument that the loss was felt in the place of the unlawful conduct, stating that "Maryland's choice of law rules for negligence claims are settled"—the court was bound to apply the law of the state where the injury, the financial loss, occurred. *Id.* at 442–

[7] That property damage to ocular tissue may have taken place in a number of other states does not persuade the court to apply the law of each of those states. The result of the property damage is primarily a loss in service fees that would have been collected by KeraLink, an effect largely felt in Maryland. And at any rate, at least some of the property damage took place in Maryland (ECF No. 118-4, Buckley Dep. at 97–98), and the laws of each state which Geri-Care seeks to have applied are not meaningfully distinct from Maryland with respect to strict liability and negligence claims. California, Connecticut, the District of Columbia, Florida, Maine, New Hampshire, Rhode Island, Texas, and Vermont have, like Maryland, explicitly adopted the Restatement (Second) of Torts § 402A. *See Brown v. Superior Ct.*, 44 Cal. 3d 1049, 1056–57 (1988); *Izzarelli v. R.J. Reynolds Tobacco Co.*, 321 Conn. 172, 184 (2016); *Word v. Potomac Elec. Power Co.*, 742 A.2d 452, 459 (D.C. 1999); *West v. Caterpillar Tractor Co.*, 336 So. 2d 80, 87 (Fla. 1976); *Est. of Pinkham v. Cargill, Inc.*, 55 A.3d 1, 5–6 (Me. 2012); *Buttrick v. Arthur Lessard & Sons, Inc.*, 110 N.H. 36, 38–39 (1969); *Ritter v. Narragansett Elec. Co.*, 109 R.I. 176, 191 (1971); *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009); *Zaleskie v. Joyce*, 133 Vt. 150, 155 (1975). And though Virginia and Massachusetts do not recognize strict liability as a stand-alone tort, the legislatures of those states have modified liability for negligence and/or breach of implied warranty such that those causes of actions encompass the same strict liability principles of most other states. *See Com. v. Johnson Insulation*, 425 Mass. 650, 653–54 (1997) (noting that "the Legislature . . . has expressed its intent that this warranty should establish liability as comprehensive as that to be found in other jurisdictions that have adopted the tort of strict product liability"); Va. Code § 8.01-318 (abolishing requirement of privity between parties in cases brought against the manufacturer or seller of goods to recover damages for breach of warranty and negligence claims); *Powell v. Diehl Woodworking Mach., Inc.*, 198 F. Supp. 3d 628, 632–33 (E.D. Va. 2016) (summarizing law of negligence in products liability cases in Virginia).

43.[8] *See also Johnson v. Oroweat Foods Co.*, 785 F.2d 503, 511 (4th Cir. 1986) ("The place of injury is the place where the injury was suffered, not where the wrongful act took place.").

The cases cited by Geri-Care are inapposite. Most of them are cases which address the difficulties in certifying class actions brought by individuals who suffered personal injuries from use of a product where the individual injuries were felt in multiple states. *See Angeletti*, 358 Md. at 747–48; *State of W. Virginia ex rel. Chemtall Inc. v. Madden*, 607 S.E.2d 772, 780 (W. Va. 2004); *In re Bridgestone/Firestone, Inc.*, 288 F.3d 1012, 1016–18 (7th Cir. 2002). This is not a proposed class action. And *Lloyd v. Gen. Motors Corp.*, 275 F.R.D. 224, 232 n.8 (D. Md. 2011) supports KeraLink's position, not Geri-Care's. In a footnote in that opinion, the court observed that a financial loss resulting from a product defect may occur in the place where the purchase was made. *Id.* There is no dispute that KeraLink initiated purchase orders for the Stradi-Paks that contained the eyewash and paid for the Stradi-Paks in Maryland. (ECF No. 123-26, Buckley Aff. ¶¶ 31–32). Accordingly, the court will apply Maryland law to KeraLink's strict products liability and negligence claims.

Stradis adopts KeraLink's choice of law arguments and contends that therefore the court also should apply Maryland law to Stradis's strict liability claims against Geri-Care. But it is not clear that any of Stradis's alleged injuries, whether a risk of physical injury from use of the eyewash or economic loss, (*see* ECF No. 84, Stradis Amend. Third Party Compl. ¶¶ 45, 53, 58), occurred in Maryland, as Stradis's principal place of business is in Georgia, (*see* ECF No. 118-5,

[8] In so holding, the court in *Bank of Louisiana* distinguished *Cremi v. Brown*, 955 F. Supp. 499, 522–24 (D. Md. 1997), a case on which Geri-Care relies. The *Cremi* court decided that under the *lex loci delicti* doctrine, the injury in a negligent misrepresentation or fraud claim is where the wrongful act took place, as opposed to where the injury was felt. *Id.* The *Bank of Louisiana* court reasoned that the justifications used by the court in *Cremi* did not apply because there were no misrepresentation claims at issue. 438 F. Supp. 3d at 442. The court agrees with that analysis.

A. Sokol Dep. at 15).[9] Accordingly, the court will apply Georgia law to Stradis's strict liability claims. The court will apply Maryland law to Stradis's indemnification and contribution claims, however, as they arise out of KeraLink's tort-based claims against Geri-Care and Stradis, which are governed by Maryland law. *See Sand Canyon Corp. v. Bank of N.Y. Mellon*, No. CV GLR-19-2815, 2021 WL 3172274, at *7 n.4 (D. Md. July 27, 2021).[10]

**b. Breach of Warranty Claims**

KeraLink and Stradis's breach of warranty claims are based in contract. "In a contract claim, Maryland courts follow the rule of *lex loci contractus*, applying the substantive law of the state where the contract was formed, unless there is a choice-of-law provision in the contract." *Allstate Ins. Co. v. Rochkind*, 381 F. Supp. 3d 488, 498 (D. Md. 2019) (citing cases). A "contract is made where the last act necessary to make the contract binding occurs." *Id.* The parties do not contend there were any choice of law provisions in any purchase agreements for the eyewash. When the parties have not agreed as to the applicable law, Maryland's Uniform Commercial Code governs claims for breach of warranty arising out of "transactions bearing an appropriate relation to this State." Md. Code Ann., Com. Law § 1–301(b). In interpreting South Carolina's nearly identical UCC provision, the Fourth Circuit Court of Appeals has observed that "[t]he majority of courts . . . [have] defined 'appropriate relation' in accord with the dominant trend in modern conflict of laws analysis, under which the law of the state with the 'most significant relationship' to the matter at issue is applied." *In re Merritt Dredging Co., Inc.*, 839 F.2d 203, 206 (4th Cir. 1988). In making this determination, courts in this district have looked to a number of non-exclusive factors, including: the place of contracting, the place of negotiation, the place of

[9] Stradis does not attempt to show where an alleged risk of physical injury occurred.
[10] Unpublished opinions are cited for the soundness of their reasoning and not for any precedential value.

performance, the location of the subject matter of the contract, the place where the defective product was maintained, the place of injury, and the residence of the parties. *See Niagara Transformer Corp. v. Baldwin Techs., Inc.*, No. CIV.A. DKC 11-3415, 2013 WL 2919705, at *5 (D. Md. June 12, 2013) (citing Restatement (Second) of Conflicts of Laws § 188 (2012)); *H & M Co. v. Tech. Heat Transfer Servs., Inc.*, No. CIV.A. TDC-14-1518, 2015 WL 1472000, at *2 (D. Md. Mar. 30, 2015) (citing *Thornton v. Cessna Aircraft Co.*, 886 F.2d 85, 90 (4th Cir.1989)).

With regard to KeraLink's breach of warranty claim against Stradis, KeraLink and Stradis agree that Maryland law applies. It is undisputed that KeraLink initiated and signed purchase orders for the Stradi-Paks that contained the eyewash and paid for the Stradi-Paks in Maryland. (ECF No. 123-26, Buckley Aff. ¶ 31–32). Maryland is the place of the sale, where the contract was formed, and, from KeraLink's perspective, the place of negotiation. *See Volkswagen of Am., Inc. v. Young*, 272 Md. 201, 220 (1974) ("The law of the place of the sale determines the extent and effect of the warranties which attend the sale."). As discussed above, the place of the injury is largely in Maryland, where KeraLink resides. Accordingly, the factors relevant to the analysis under § 1-301(b) overwhelmingly favor Maryland law, and the court will thus apply Maryland law.

As for KeraLink's breach of warranty claims against Geri-Care, KeraLink did not purchase the eyewash directly from Geri-Care, but the analysis of the relevant factors under § 1-301(b) is largely the same. Maryland has a significant relationship to the matter given KeraLink's residence, the place of injury, and the place of the sale to KeraLink. But Geri-Care argues that either Florida, New York, or Georgia law should govern because, it alleges, most of the contamination of tissue occurred in Florida; Geri-Care is a New York company and it contracted for the eyewash with Henry Schein in New York; and Stradis assembled the custom Stradi-Paks in Georgia. (ECF No.

118-1, Geri-Care Mot. as to KeraLink at 24–26). Again, the court disagrees that it must apply the law of each state in which tissue was exposed to the eyewash. KeraLink had no interactions with Henry Schein, a non-party, and the fact that Geri-Care and Stradis have their principal places of business in other states does not outweigh Maryland's significant relationship to this matter discussed above.

Stradis again adopts KeraLink's choice of law arguments concerning its breach of warranty claims against Geri-Care and argues that Maryland law should apply, and Geri-Care repeats its arguments in favor of Florida, New York, or Georgia law. Stradis's principal place of business is in Georgia and the packaging and assembling of the Stradi-Paks occurred there. (ECF No. 128-5, A. Sokol Dep. at 15). As discussed above, Stradis's economic loss, its injury, occurred in Georgia. Stradis also did not purchase the eyewash directly from Geri-Care; rather, Geri-Care supplied the eyewash to InSource, which then sold it to Stradis. Neither Geri-Care nor Stradis have presented evidence of the place of sale, the place of negotiation, the place of performance, the location of the subject matter of the contract, or the place where the defective product was stored in connection with Stradis's purchase from InSource (though it may be reasonable to assume that Stradis stored the eyewash in Georgia, where it was repackaged into the Stradi-Paks). Stradis's breach of warranty claims are related to Maryland only in that the eyewash was sold to KeraLink, a resident of Maryland. With this limited information, the court believes that Georgia has the most significant relationship to Stradis's breach of warranty claims against Geri-Care and will apply Georgia law.

**B. KeraLink's Claims**

KeraLink has moved for summary judgment on its strict liability and breach of warranty claims against Geri-Care and Stradis, and Geri-Care and Stradis have each moved for summary judgment on KeraLink's claims against them: strict liability, breach of warranty, and negligence

as to Geri-Care, and strict liability and breach of warranty as to Stradis. The court will first address the claims applicable to both defendants and will then turn to KeraLink's negligence claim against Geri-Care.

**a. Strict Products Liability (Stradis and Geri-Care)**

Maryland has "embraced the concept of strict liability as a basis for products liability and expressly adopted the elements contained in the Restatement (Second) of Torts § 402A (1965)." *May v. Air & Liquid Sys. Corp.*, 446 Md. 1, 23 (2015) (citing *Phipps v. Gen. Motors Corp.*, 278 Md. 337, 352–53 (1976)). Section 402A provides:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> (a) the seller is engaged in the business of selling such a product, and
>
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
>
> (2) The rule stated in Subsection (1) applies although
>
> (a) the seller has exercised all possible care in the preparation and sale of his product, and
>
> (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement (Second) of Torts § 402A (1965). In order to recover, KeraLink must establish that that "(1) the product was in [a] defective condition at the time that it left the possession or control of the seller, (2) that it was unreasonably dangerous to the user or consumer, (3) that the defect was a cause of the injuries, and (4) that the product was expected to and did reach the consumer without substantial change in its condition." *Phipps*, 278 Md. at 344.

KeraLink has offered evidence to support each element of its strict products liability claim against Geri-Care and Stradis. First, testing conducted by Stradis and Geri-Care revealed that the eyewash was contaminated with *Achromobacter xylosoxidans* when it left Geri-Care's and Stradis's possession. (ECF 118-6, Kleyn Dep. at 90; ECF No. 123-13 at 5; ECF No. 123-17 at 2; 123-18 at 10–16; 123-19 at 3). Second, the record supports an inference that the product is

unreasonably dangerous if used to irrigate corneal tissue that is then used for transplantation into a living patient. Kareway's FDA recall notice of the eyewash indicated that the contamination "compromises sterility" and its use "has a potential to result in infection that may be sight-threatening," (ECF No. 123-21). KeraLink's hybrid fact-expert witness, Thomas Buckley, is expected to testify that peer-reviewed literature indicates that the species *Achromobacter xylosoxidans* can cause serious infection to patients. (ECF No. 123-26, Ex. A to Buckley Aff. at 4; ECF No. 123-27; ECF No. 123-28).[11] Third, it is undisputed that as a result of the contamination, KeraLink could not use the eyewash or any corneal tissue that came into contact with it, resulting in damage to the tissue and financial loss. And finally, no party contends that the eyewash did not reach KeraLink without substantial change to its condition.

Stradis does not dispute the above evidence, but argues that KeraLink's claim is barred by the sealed container defense. Geri-Care also asserts the sealed container defense and makes the

[11] Geri-Care raises various objections to this evidence in connection with its argument that KeraLink cannot show that the eyewash posed a *severe* risk of personal injury for purposes of demonstrating an exception to the economic loss doctrine, discussed below. (*See* ECF No. 133, Geri-Care Combined Opp./Reply to Stradis & KeraLink Mots. at 14–15). These arguments include that Kareway's recall notice is inadmissible hearsay and that Mr. Buckley is not qualified to testify regarding the hazards posed by *Achromobacter xylosoxidans.* But KeraLink has demonstrated that, if offered at trial, the FDA recall notice is likely admissible. Courts in the Fourth Circuit "routinely take judicial notice of information contained on state and federal government websites," because those websites generally are sources whose accuracy cannot reasonably be questioned. *United States v. Garcia*, 855 F.3d 615, 621 (4th Cir. 2017). Furthermore Mr. Buckley is noticed as a hybrid fact/expert witness qualified to testify "as to the procedures for the recovery, handling, and processing corneal tissue for transplant" governed by the FDA and the EBAA, and "ocular recovery and transplant methodologies, principles, practices, and the need for sterile eye wash during recovery," (ECF No. 123-29 at 5–6), and is a co-author of one of the articles in the record discussing the risk of infection from *Achromobacter xylosoxidans*, (ECF No. 123-26, Ex. A to Buckley Aff.). At the very least, Mr. Buckley would likely be able to discuss his knowledge of the article and, drawing on his experience in the ocular recovery and transplantation industry, explain his understanding of the FDA regulations which precluded the use of the tissue exposed to the eyewash based on a risk of the spread of communicable disease. *See* 21 C.F.R. §§ 1271.215 (recovery of HCT/Ps).

additional argument that KeraLink's strict liability and negligence claims are barred by the economic loss doctrine.

**i. Sealed Container Defense**

The sealed container defense is meant to make liability for damages and injury caused by a defective product lie with the manufacturer, not the retailer. *See Liesener v. Weslo*, Inc., 775 F.Supp. 857, 859 (D. Md. 1991). Section 5–405(b) of the Maryland UCC provides that a "seller" of the product may avoid liability for property damage or personal injury caused by the defective design or manufacture of a product if it can establish that:

> (1) The product was acquired and then sold or leased by the seller in a sealed container or in an unaltered form; (2) The seller had no knowledge of the defect; (3) The seller in the performance of the duties he performed or while the product was in his possession could not have discovered the defect while exercising reasonable care; (4) The seller did not manufacture, produce, design, or designate the specifications for the product which conduct was the proximate and substantial cause of the claimant's injury; and (5) The seller did not alter, modify, assemble, or mishandle the product while in the seller's possession in a manner which was the proximate and substantial cause of the claimant's injury.

Md. Code Ann., Cts. & Jud. Proc. § 5–405(b). *See also Mirchandani v. Home Depot U.S.A., Inc.*, 470 F. Supp. 2d 579, 581 (D. Md. 2007). But the defense does not apply in the following situations:

> (1) The manufacturer is not subject to service of process under the laws of this State or the Maryland Rules; (2) The manufacturer has been judicially declared insolvent in that the manufacturer is unable to pay its debts as they become due in the ordinary course of business; (3) The court determines by clear and convincing evidence that the claimant would be unable to enforce a judgment against the product manufacturer; (4) The claimant is unable to identify the manufacturer; (5) The manufacturer is otherwise immune from suit; or (6) The seller made any express warranties, the breach of which were the proximate and substantial cause of the claimant's injury.

Md. Code Ann., Cts. & Jud. Proc. § 5–405(c).

KeraLink argues that the defense does not apply to either defendant because neither can satisfy its fourth or fifth elements, and even if they were able to, a number of exceptions to the

defense would apply. The court will first address whether Geri-Care or Stradis is a "manufacturer" under the statute and thus unable to assert the sealed container defense.

The statute provides that a "manufacturer" means "a designer, assembler, fabricator, constructor, compounder, producer, or processor of any product or its component parts" and "includes an entity not otherwise a manufacturer that imports a product or otherwise holds itself out as a manufacturer." Md. Code Ann., Cts. & Jud. Proc. § 5-405(a)(2). KeraLink contends that Geri-Care designed the eyewash and imported it; that Stradis is an assembler; and that each defendant held itself out as a manufacturer of the eyewash.

Geri-Care argues that it is not a manufacturer because it received the eyewash from Kareway pre-packaged, sealed, and labeled; it did not open or alter the eyewash before selling it to InSource; it was not aware of and could not have reasonably discovered the contamination at the time of distribution; and it had no involvement in choosing the contents of the eyewash. These arguments do not address the clear record in this case that Geri-Care at least held itself out as a manufacturer, and thus is deemed to be one for the purposes of the sealed container defense. Geri-Care's corporate representative's unequivocal testimony was that the company wanted the public to think it manufactured the eyewash. (ECF No. 118-6, Kleyn Dep. at 18, 114). Geri-Care furthered that goal by providing a Geri-Care logo and distribution statement to Kareway to place on the eyewash bottles and by naming itself (and no other company) as the distributor of the eyewash on the label and as the registrant to the FDA. (ECF No. 118-6, Kleyn Dep. at 11–14, 77; ECF No. 123-4; ECF No. 123-6; ECF No. 123-9). There was no way for a purchaser of the eyewash to know that Geri-Care was not the manufacturer or that it did not have facilities in Korea, and nothing prevented Geri-Care from correcting an assumption that it was the manufacturer. (ECF No. 118-

6, Kleyn Dep. at 113, 114). In such circumstances, under the statute Geri-Care is precluded from asserting the sealed container defense.

KeraLink argues that Stradis also held itself out as a manufacturer of the eyewash when it affixed to the Stradi-Paks a label that specifically stated: "Manufactured & Distributed by Stradis Healthcare, LLC." (ECF No. 123-31; ECF No. 123-33). But the label is for the entire Stradi-Pak, not the eyewash itself, which is labeled "Distributed by Geri-Care Pharmaceuticals, LLC" and has a Geri-Care branded logo. (ECF No. 123-31; ECF No. 123-33; ECF No. 123-5). Stradis admits that it assembled the Stradi-Paks in that it removed each of the component parts, including the eyewash, from their original packaging and repackaged them into Stradi-Paks. The court does not agree with KeraLink that this makes Stradis an "assembler" of the eyewash, as Stradis's conduct in no way affected the content of the eyewash itself and there is no evidence that the Stradi-Paks themselves were defective, contaminated, or caused KeraLink's injuries. Stradis has demonstrated it is entitled to the sealed container defense in all other respects. It acquired the eyewash from InSource sealed, and repackaged it in the same form without altering or modifying the contents of the eyewash. Stradis did not know of the contamination and relied on Geri-Care's assertion that the product was sterile. (ECF No. 118-5, Sokol Dep. at 105, 142–43. 157–58, 160). But, as the court will explain below, KeraLink has demonstrated that Stradis made an express warranty regarding the attributes of the eyewash, the breach of which was a proximate and substantial cause of KeraLink's injury. Thus the exception under Md. Code Ann., Cts. & Jud. Proc. § 5–405(c)(6) applies to preclude Stradis from asserting the sealed container defense.

**ii. Economic Loss Doctrine**

Losses in Maryland products liability claims fall into three categories: "(1) personal injuries, (2) physical harm to property other than the product itself, or (3) economic loss suffered

when the product fails to meet the contractual expectations of the purchaser." *Morris v. Osmose Wood Preserving*, 340 Md. 519, 531 (1995). As a general rule, plaintiffs cannot recover in tort for losses in the third category, purely economic losses. *Id.*; *U.S. Gypsum Co. v. Mayor & City Council of Baltimore,* 336 Md. 145, 156 (1994). The rule does not apply when the plaintiff is seeking compensation for damage to property, other than the product itself, caused by the alleged defectiveness of a product. *A.J. Decoster Co. v. Westinghouse Elec. Corp.*, 333 Md. 245, 251–52, 259–60 (1994). And recovery for economic loss is permitted "when those losses are coupled with a serious risk of death or personal injury resulting from a dangerous condition. . . to encourage correction of the dangerous condition." *Morris*, 340 Md. at 535.

KeraLink contends that both of the above exceptions apply in this case—it suffered damage to property when recovered ocular tissue was rendered unusable by the eyewash, and the eyewash posed a serious risk of personal injury when exposed to patients receiving the ocular tissue. Geri-Care contends that this court should not recognize the ocular tissue as property and that no serious risks existed.

The definition of property under Maryland law broadly encompasses "real, personal, mixed, tangible or intangible property of every kind." Md. Rule 1-202(v); *see also Dua v. Comcast Cable of Maryland, Inc.*, 370 Md. 604, 631 n.10 (2002). The ocular tissue is undoubtedly a tangible object, and a gift of tissue to KeraLink is, under the Maryland Anatomical Gift Act, accompanied by certain rights and interests in the donated tissue.

The Maryland Anatomical Gift Act has existed in some form since 1968. *See Scarbrough v. Transplant Res. Ctr. of Maryland*, 242 Md. App. 453, 459 (2019). The current iteration of the Act "applies to an 'anatomical gift,' which it defines as the 'donation of all or part of a human body to take effect after the donor's death for the purpose of transplantation, therapy, research, or

education.'" *Id.* (quoting Md. Code Ann., Est. & Trusts § 4-501(c)). The Act circumscribes, but does not completely prohibit, the use, transfer, or possession of parts of the human body. Upon receipt of an anatomical gift, KeraLink may use the donated tissue for transplantation, therapy, research, or education. *Id.* § 4-509(d). It may not, for valuable consideration, sell the tissues for transplantation or therapy, but it may "charge a reasonable amount of money for the removal, processing, preservation, quality control, storage, transportation, implantation, or disposal of a part." *Id.* § 4-513. The gift of the tissue thus gives KeraLink rights in service fees for various actions with respect to the tissue and the right to use it in transplantation, therapy, research, or education. Geri-Care does not explain why these rights are not cognizable property interests.

The cases on which Geri-Care relies to argue that KeraLink has no property rights in the ocular tissue simply confirm what the Anatomical Gift Act already instructs— property rights in tissue, body parts, or material once contained within the human body may be limited in various ways, but they nonetheless exist. For example, a number of courts have precluded plaintiffs from maintaining common law conversion claims against hospitals or organ donation networks for retaining organs or tissue in which the plaintiffs claimed an interest, *see Colavito v. New York Organ Donor Network, Inc.*, 356 F. Supp. 2d 237, 244 (E.D.N.Y. 2005), *aff'd in part, question certified*, 438 F.3d 214 (2d Cir. 2006), *certified question answered*, 8 N.Y.3d 43 (2006), *and aff'd*, 486 F.3d 78 (2d Cir. 2007); *Moore v. Regents of Univ. of California*, 51 Cal. 3d 120, 142–147 (1990);*cf United States v. Arora*, 860 F. Supp. 1091, 1099 (D. Md. 1994), *aff'd*, 56 F.3d 62 (4th Cir. 1995) (holding that the physical destruction of a new cell line used for research may support a conversion claim by the researcher who created the cells). As the California Supreme Court observed in *Moore*, the trend against the recognition of such conversion claims is not "surprising, since [state] laws governing such things as human tissues, . . . [including] corneal tissue, . . . deal

with human biological materials as objects sui generis, regulating their disposition to achieve policy goals rather than abandoning them to the general law of personal property." *Moore*, 51 Cal. 3d at 137 (footnotes omitted).

*Palermo v. LifeLink Found., Inc.*, 152 So. 3d 1177, 1181 (Miss. Ct. App. 2014), *aff'd*, 152 So. 3d 1099 (Miss. 2014) and *Condos v. Musculoskeletal Transplant Found.*, 208 F. Supp. 2d 1226, 1229–30 (D. Utah 2002) similarly demonstrate that state law may constrain property rights in anatomical parts. In both cases, state laws prohibiting the sale of (but not destroying all property rights in) anatomical parts precluded plaintiffs from alleging that human tissue or body parts *themselves* can be defective products for purposes of a products liability action. *See id.* But those cases say nothing about the ability of a plaintiff to recover damages for the destruction or contamination of human parts by a defective product. And *Venner v. State* only further proves KeraLink's argument that Maryland recognizes some property rights in human tissue or body parts. 30 Md. App. 599, 626–27 (1976), *aff'd*, 279 Md. 47 (1977). In that case, the court assumed that a defendant *did* have a property right in excrement and drug balloons discharged from his body, but that he had no right to challenge law enforcement's warrantless seizure of the material because he had abandoned it. *Id.*

The court is persuaded that KeraLink had property interests in its ocular tissue and suffered property loss when the tissue was contaminated by the eyewash, resulting in damages in the form of lost service fees. As KeraLink is not claiming purely economic loss, the economic loss doctrine does not bar its tort claims. *See A.J. Decoster*, 333 Md. at 260 (permitting recovery for replacement costs of chickens killed by a defective electrical switch); *Cash & Carry Am., Inc. v. Roof Sols., Inc.*, 223 Md. App. 451, 468, (2015) (permitting recovery for defendant's misuse of a torch in performing the roof replacement work, resulting in the roof catching fire).

Accordingly, because Geri-Care and Stradis have failed to demonstrate that either the sealed container defense or the economic loss doctrine applies to bar KeraLink's claims, and because the record supports a finding of strict liability, the court will award summary judgment to KeraLink on its strict liability claims.[12]

**b. Breach of Warranty (Stradis and Geri-Care)**

KeraLink brings claims of breach of implied and express warranty against Geri-Care and Stradis. The court will first address KeraLink's claims for breach of express warranty and then turn to the implied warranty claims, breach of the implied warranty of merchantability and breach of the implied warranty of fitness for a particular purpose.

**i. Breach of Express Warranty**

In order to establish a breach of express warranty in Maryland, KeraLink is required to establish that (1) a warranty existed; (2) the product did not conform to the warranty; and (3) the breach proximately caused the injury or damage. *Robinson v. Am. Honda Motor Co., Inc.*, 551 F.3d 218, 223 (4th Cir. 2009). A seller can create an express warranty by making any of the following representations:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
> (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

*Morris v. Biomet, Inc.*, 491 F. Supp. 3d 87, 107 (D. Md. 2020) (quoting Md. Code Ann., Com. Law § 2-313(1)). "It is not necessary to the creation of an express warranty that the seller use formal words such as 'warrant' or 'guarantee' or that he have a specific intention to make a

[12] The court does not reach the question of whether the contamination of the eyewash created a serious risk of personal injury, which also would permit tort recovery for KeraLink's losses.

warranty, but an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty." Md. Code Ann. Com. Law § 2-313(2). Affirmations of fact which are included in the label of a product or in packaging inserts may constitute express warranties. *See, e.g.*, *Rite Aid Corp. v. Levy-Gray*, 391 Md. 608, 624–25 (2006) (statements in package insert that a drug could be taken with food or milk formed the basis of express warranty claim); *Starr v. VSL Pharms., Inc.*, 509 F. Supp. 3d 417, 444 (D. Md. 2020) (product information sheet within the packaging which contained statements as to the quality of the product could constitute an express warranty).

KeraLink argues that Stradis made express warranties that the eyewash was "sterile." Geri-Care indicated the eyewash was a "Sterile Eye Irrigating Solution" and a "sterile solution" on the box of the eyewash and on the eyewash bottle itself. (ECF No. 123-9; ECF No. 123-34). Stradis included with each Custom Stradi-Pak a packaging insert that described the entire Stradi-Pak as "Sterile: Unless Open or damaged" and the eyewash as a "sterile eye wash." (ECF No. 123-31; ECF No. 123-33).

Though Geri-Care made an affirmation of fact that the eyewash was sterile, KeraLink concedes that the court must award summary judgment to Geri-Care on the breach of express warranty claim because KeraLink is not in privity of contract with Geri-Care. Maryland has abolished the privity requirement in cases of breach of express warranty only where the consumer has suffered personal injury by breach of the warranty. *See Morris*, 340 Md. at 545.

As for KeraLink's breach of express warranty claim against Stradis, Stradis argues that its description of the product as "sterile eye wash" cannot be regarded as an express warranty because Stradis simply listed the eyewash in the package insert by the name of the product given to it by Geri-Care. There are two problems with this argument. First, Stradis was aware that KeraLink

needed a sterile eyewash to be included in the Stradi-Paks for its recovery procedures, and it selected the Geri-Care eyewash in response to that request. (ECF No. 118-5, Sokol Dep. at 144–46). A jury could plausibly infer that Stradis's inclusion of the product in the Stradi-Pak supports a finding that Stradis affirmed the eyewash was sterile. Second, Stradis has not provided any authority for the proposition that it is a defense to liability that it merely repeated the affirmation or promise of another seller in the distribution chain. Thus, Stradis has failed to create an issue of material fact regarding whether it warranted that the eyewash was "sterile." As Stradis concedes that the eyewash was not sterile when it left Stradis's control and that KeraLink sustained damages as a result of the eyewash's failure to conform to the representation that the product was sterile, the court will award summary judgment to KeraLink on its breach of express warranty claim against Stradis.

**ii. Breach of Implied Warranty**

Maryland recognizes two types of implied warranties in the sale of goods: merchantability and fitness for a particular purpose. KeraLink argues that Stradis and Geri-Care are liable for breach of the implied warranty of merchantability and that Stradis also is liable for breach of the implied warranty of fitness for a particular purpose.

**1. Implied Warranty of Merchantability**

Under the Maryland UCC § 2-314, "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." Md. Code Ann., Com. Law § 2-314(1). For this implied warranty of merchantability the "requirement of privity is abolished as between the buyer and the seller in any action brought by

the buyer." *Id.* § 2-314(1)(b).[13] The elements of breach of the implied warranty of merchantability are similar to those for breach of express warranty. *See Lloyd v. Gen. Motors Corp.*, 397 Md. 108, 157 (2007).

As with breach of express warranty, Stradis's sole defense to the breach of implied warranty of merchantability claim is that it made no warranties. "To be merchantable, . . . goods must at least be fit for the ordinary purposes for which they are sold and conform to any promises or affirmations of fact made on the container or label." *Virgil v. Kash N'Karry Service Corp.*, 61 Md. App. 23, 29 & n.2 (1984) (citing Md. Code Ann., Com. Law §§ 2-314(2)(c), (f)). As discussed above, KeraLink has submitted evidence that Stradis made an affirmation of fact separate from Geri-Care's label that the eyewash was "sterile," an affirmation to which the eyewash failed to conform, and Stradis has not rebutted this evidence.

Geri-Care does not dispute that its affirmation that the eyewash was "sterile" constitutes a warranty, but instead makes two arguments in an attempt to create a dispute of material fact regarding whether the failure of the eyewash to conform to the warranty proximately caused KeraLink's injuries. First, Geri-Care contends that there is a factual dispute concerning whether the eyewash was sterile when it left Geri-Care's possession and was shipped to InSource, because (1) Geri-Care did not open the containers of eyewash, (2) one test performed by Kareway showed that the eyewash was sterile, and (3) the eyewash passed through two other entities (InSource and Stradis) before reaching KeraLink. Second, Geri-Care argues that Stradis's decision to include Geri-Care eyewash in a package that would be used in surgical procedures and to make an

[13] For this reason, Geri-Care's defense that KeraLink's breach of implied warranty fails for lack of privity is not meritorious. The court declines to adopt Geri-Care's interpretation that the requirement of showing privity for a breach of express warranty claim extends to a breach of implied warranty of merchantability claim where the claim is based on an argument that the product does not conform to promises or affirmations of fact on a label. (*See* ECF No. 133 at 21).

independent warranty as to the sterility of the eyewash was a superseding cause. Neither argument is persuasive.

Geri-Care's own corporate representative admitted that she did not believe or rely on Kareway's initial testing that indicated the eyewash was sterile once Geri-Care received results from its own independent testing of product in its possession. (ECF No. 118-6, Kleyn Dep. at 90). All other evidence confirms that the eyewash was sealed when it left Geri-Care's possession, when it left InSource's and Stradis's possession, and also when Stradis repackaged the bottles into the Stradi-Paks. While Geri-Care did not necessarily expect that the eyewash would be used in surgical procedures, (*id.* at 82), Geri-Care acknowledges that the product is intended for use in the eye and it has never informed a customer that the eyewash is inappropriate for ocular tissue recovery, (*id.* at 83). And it agreed that the customer "is expecting to have a sterile product . . . if that's what you're claiming," (*id.* at 25) and that the eyewash would need to be sterile if used on a deceased person, (*id.* at 119). On this record, no reasonable jury could conclude that the eyewash was contaminated only after it left Geri-Care's possession or that Geri-Care did not foresee the use of its product in the eye or eye tissue.

**2. Implied Warranty of Fitness for a Particular Purpose**

For KeraLink to recover from Stradis for a breach of the implied warranty of fitness for a particular purpose, it must show that Stradis (1) had reason to know KeraLink's particular purpose; (2) had reason to know that KeraLink was relying on Stradis's skill or judgment to furnish appropriate goods; and (3) KeraLink relied on Stradis's skill and judgment. *Ford Motor Co. v. Gen. Acc. Ins. Co.*, 365 Md. 321, 342 (2001). A particular purpose is one "distinguishable from the normal use of the goods; the purpose must be peculiar to the buyer as distinguished from the ordinary or general use to which the goods would be put by the ordinary buyer." *Id.* at 343

(alterations and internal quotation marks omitted). In support of this claim, KeraLink cites Stradis's marketing that it has "expertise in eye banking and corneal transplantation" and that its products were "designed to help recover the highest quality tissue." (ECF No. 123-35 at 2). Stradis's corporate representative also was aware that KeraLink was ordering Custom-Stradi-Paks with the eyewash in order to perform ocular tissue recovery. (ECF No. 118-5, Sokol Dep. at 19-20, 54). Again, Stradis's defense is that it cannot be liable because it only repeated the warranties made by Geri-Care. But this misses the point that Stradis was aware KeraLink needed a sterile eyewash included in the Stradi-Pak for ocular recovery procedures and that Stradis selected the Geri-Care eyewash as that product, representing that it was the sterile eyewash needed for those procedures. (*Id.* at 18–23, 144–46). The court finds there is no dispute of material fact that Stradis impliedly warranted that the eyewash was sterile and suitable for use in KeraLink's ocular tissue recovery procedures.

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Accordingly, the court will grant KeraLink's motion for summary judgment as to all of its breach of warranty claims against Stradis and as to its breach of the implied warranty of merchantability claim against Geri-Care. The court will grant Geri-Care's motion for summary judgment as to KeraLink's breach of express warranty claim against it.

**c. Negligence (Geri-Care)**

In order to succeed on its negligence claim, KeraLink must prove (1) that Geri-Care was under a duty to protect KeraLink from injury, (2) that Geri-Care breached that duty, (3) that KeraLink suffered actual injury or loss, and (4) that the loss or injury proximately resulted from Geri-Care's breach of the duty. *Washington Metro. Area Transit Auth. v. Seymour*, 387 Md. 217, 223 (2005). KeraLink's theory of negligence in this case is that Geri-Care had a duty as a seller of

the eyewash, knowing that customers required the eyewash to be sterile, to test samples of the eyewash before distributing it. KeraLink contends that had Geri-Care tested the eyewash, it would have discovered the contamination before distribution, preventing KeraLink's injuries. Geri-Care argues it is entitled to summary judgment on KeraLink's negligence claim because (1) expert testimony is necessary to establish the standard of care, and KeraLink has not designated such an expert; and (2) even if expert testimony is not required, no reasonable jury could conclude that Geri-Care had an obligation to conduct testing.[14]

Maryland often requires expert testimony to establish the standard of care owed by a professional, such as a medical provider, an attorney, or a bank, or to establish other complex or technical matters that are "beyond the ken of the average layperson." *See, e.g.*, *Access Limousine Serv., Inc. v. Serv. Ins. Agency, LLC*, No. CV TDC-15-3724, 2016 WL 6126267, at *7 (D. Md. Oct. 19, 2016); *Schultz v. Bank of Am., N.A.*, 413 Md. 15, 28 (2010); *Rodriguez v. Clarke*, 400 Md. 39, 71 (2007); *Kash N' Karry*, 61 Md. App. at 31 ("The general rule is well established that expert testimony is only required when the subject of the inference is so particularly related to some science or profession that it is beyond the ken of the average layman"). The court does not believe expert testimony regarding the medical product's industry's approach to testing is necessary to help a jury determine whether Geri-Care was negligent in failing to test the eyewash for sterility A manufacturer may be held liable when it "should recognize" that the product creates an unreasonable risk of physical harm, which may create a duty to inspect the product. *Eagle-Picher Indus., Inc. v. Balbos*, 326 Md. 179, 198 (1992). This duty may extend to a non-manufacturing

[14] Geri-Care makes the additional argument that the negligence claim is barred by the economic loss doctrine. For the reasons explained above, the economic loss doctrine does not apply to this case.

seller where the seller does something more than merely to act as a conduit of goods. *See id.* at 203.

Under this standard and on this record, a reasonable jury could conclude that Geri-Care had a duty to test the eyewash for sterility. Geri-Care had the ability to conduct testing, as evidenced by its decision to do so when it began to receive complaints. That Geri-Care immediately believed its own lab results over the certificate of analysis and Kareway's initial testing showing no contamination may undermine Geri-Care's contention that it was reasonable to rely on Kareway. (ECF No. 118-6, Kleyn Dep. at 90). Geri-Care's corporate representative has testified that Geri-Care was aware of the potential dangers posed by the eyewash—namely, that it could risk the eye health of a person exposed to the eyewash. (*Id.* at 28). Whether, in light of that known risk, it was reasonable for Geri-Care to rely on Kareway's certificate of analysis that the eyewash was sterile rather than conduct its own testing is a question of fact for the jury. Accordingly, the court will deny Geri-Care's motion for summary judgment as to KeraLink's negligence claims.

**C. Stradis's Claims**

**a. Indemnification and Contribution**

Stradis brings claims for indemnification and contribution against both Geri-Care and InSource.

Under the Uniform Contribution Among Tort-Feasors Act ("UCATA"), Md. Code Ann., Cts. & Jud. Proc. § 3-1401 *et seq.*, a right of contribution exists among joint tortfeasors, defined as "two or more persons jointly or severally liable in tort for the same injury to person or property, whether or not judgment has been recovered against all or some of them." *Id.* §§ 3-1401(c), 3-1402(a). The right is "predicated on a third-party's direct liability to the plaintiff." *Gables Constr.*,

*Inc. v. Red Coats, Inc.*, 468 Md. 632, 651 (2020). "A joint tortfeasor must be legally responsible to the plaintiff for his or her injuries." *Id.* (quoting *Montgomery Cnty. v. Valk Mfg. Co.*, 317 Md. 185, 200 (1989)).

Maryland also recognizes rights to indemnity that may arise from (1) an express contractual provision, (2) implication by fact arising from a special relationship between the parties, or (3) implication by law, also characterized as "tort indemnity." *Pulte Home Corp. v. Parex, Inc.*, 403 Md. 367, 381–82 (2008). It is this latter form of indemnity that Stradis seeks. "Maryland law recognizes a right to indemnity independent of any contract where the character of one tortfeasor's conduct is significantly different from that of another who is also liable for the same damages." *Pyramid Condo. Ass'n v. Morgan*, 606 F. Supp. 592, 595 (D. Md. 1985). The right exists when the "less culpable tortfeasor, said to be passively or secondarily negligent, pays or is held liable for damages which are properly attributable to the conduct of the more culpable co-defendant, who is primarily or actively negligent. . . . This concept is based on the distinction between "active" and "passive," however, not on relative degrees of fault." *Max's of Camden Yards v. A.C. Beverage*, 172 Md. App. 139, 148–49 (2006). Whether a tortfeasor's negligence is active or passive is determined by referring to the plaintiff's complaint against the defendant seeking to implead the third party. *Pyramid*, 606 F. Supp. at 596. "If the plaintiff's complaint alleges conduct by the third-party plaintiff that would constitute active negligence, or if it is clear from the circumstances revealed by the plaintiff's complaint that the defendant's (third-party plaintiff) liability would only arise, if at all, from proof of active negligence, there is no basis for an indemnity claim and dismissal of the claim is appropriate." *Id.*[15]

[15] If the issues in the complaint have been tried, however, the findings of fact may be determinative. *Max's of Camden Yards*, 172 Md. App. At 152-54.

**i. InSource**

InSource claims it is entitled to summary judgment on Stradis's claims for indemnification and contribution because it is not liable for any of KeraLink's injuries. KeraLink has brought no claims of negligence or strict liability against InSource and, at any rate, InSource has shown that it would be entitled to the sealed container defense in the face of such claims. The court agrees. First, when InSource acquired the eyewash from Geri-Care, the eyewash arrived in sealed bottles, packaged in individual boxes. (ECF No. 122-4 at 7). InSource did not alter, change, or repackage the eyewash in any way. (*Id.*). Stradis received the eyewash packaged and sealed in the same manner in which InSource received it. Stradis inspected the eyewash by checking for any damage, puncture or labeling issues, and the eyewash passed its inspection. (ECF No. 118-5, Sokol Dep. at 142). Second, InSource had no knowledge of the contamination, (ECF No. 122-4 at 10), and there is no allegation that it could have discovered the defect in the exercise of reasonable care. Third, there is no evidence in the record that InSource, a wholesaler, manufactured, produced, designed, assembled, or designated the specifications of the eyewash. *See* Md. Code Ann., Cts. & Jud. Proc. § 5–405(b); *Mirchandani*, 470 F. Supp. 2d at 581. And finally, none of the exceptions to the sealed container defense outlined in Md. Code Ann., Cts. & Jud. Proc. § 5–405(c) apply. As explained above, the court has identified Geri-Care as a manufacturer. Geri-Care is subject to service of process; it has not been judicially declared insolvent; the court has not determined that KeraLink would be unable to enforce a judgment against it; and it is not otherwise immune from suit. *See id.* Md. Code Ann., Cts. & Jud. Proc. §§ 5-405(c)(1)–(5). Nor has there been any claim that InSource made any express warranties. *Id.* § 5-405(c)(6). When, as here, a seller shows that he has satisfied the requirements of the sealed-container defense statute, "summary judgment shall be entered in his favor as to the original and third-party actions." *Id.* § 5-405(d)(1). Accordingly, the court will

award summary judgment to InSource on Stradis's third-party indemnification and contribution claims.

**ii. Geri-Care**

Stradis is entitled to summary judgment on its claim for contribution from Geri-Care. As explained above, Geri-Care and Stradis are both directly liable to KeraLink for strict products liability. Under the UCATA, this gives Stradis and Geri-Care a right of contribution amongst themselves as a matter of law. Md. Code Ann., Cts. & Jud. Proc. § 3-1402(a).

As for Stradis's claim for indemnification, the court looks to KeraLink's complaint to determine whether it alleges conduct by Stradis that would constitute active negligence. *See Pyramid*, 606 F. Supp. at 596. The complaint alleges Stradis sold Custom-Stradi Paks containing the eyewash it received from Geri-Care and that the eyewash was in a defective condition and unreasonably dangerous when it left Stradis's control and possession. (ECF No. 75, Second Am. Compl. ¶¶ 31–35). The complaint further alleges Geri-Care was a manufacturer of the eyewash, but did not make the same claims against Stradis. (*Id.* ¶ 30). KeraLink's claims of strict liability against Stradis are based on a failure to discover the defect in the eyewash, alleged to be manufactured by Geri-Care. Courts have described such negligence as passive or secondary and have held that there is a right to indemnity against the manufacturer. *See Pyramid*, 606 F. Supp. at 596 ("A right to indemnity is commonly recognized where, although both parties are negligent, the negligence of the indemnitee is not considered as serious as that of the indemnitor; for example, where the indemnitee's negligence is based upon a failure to inspect and thereby discover a defect in an article manufactured by the indemnitor.") (quoting *Jennings v. United States*, 374 F.2d 983, 987 n. 7 (4th Cir.1967)); *Am. Home Assur. Co. v. SUI Enter. Co.*, No. CIV. PWG 12-817, 2014 WL 1793127, at *3 (D. Md. May 5, 2014) (holding that seller of a suction diffuser used for certain

hot water piping systems was entitled to indemnification from the manufacturer where the complaint alleged that the seller "unwittingly sold a product, manufactured elsewhere, with a latent defect"). Accordingly, the court will grant Stradis's motion for summary judgment as to both contribution and indemnification from Geri-Care.

**b. Strict Products Liability**

Stradis seeks to recover for economic losses and a risk of physical injury resulting from its purchase of the contaminated eyewash from Geri-Care. Like Maryland, Georgia recognizes the economic loss rule: "a plaintiff can recover in tort only those economic losses resulting from injury to his person or damage to his property." *Gen. Elec. Co. v. Lowe's Home Centers, Inc.*, 279 Ga. 77, 78 (2005). But a plaintiff may not recover "damages for the loss of the value or use of the defective product itself, costs of repair or replacement of the defective product, or the consequent loss of profits, unaccompanied by any claim of personal injury or damage to other property." *Home Depot U.S.A., Inc. v. Wabash Nat'l Corp.*, 314 Ga. App. 360, 366 (2012). There are two recognized exceptions to this rule: the misrepresentation exception and the accident exception. *Id.* The misrepresentation exception is applicable in circumstances of concealment or fraud, which are not present here. *See Holloman v. D.R. Horton, Inc.*, 241 Ga. App. 141, 148 (1999). The accident exception applies in cases of "a sudden and calamitous event which, although it may only cause damage to the defective product itself, poses an unreasonable risk of injury to other persons or property." *Home Depot*, 314 Ga. App. at 366. This exception is more limited than Maryland's public safety exception, which applies when economic losses "are coupled with a serious risk of death or personal injury resulting from a dangerous condition." *Morris*, 340 Md. at 535. Georgia courts appear to require a "evidence of a calamity, sudden violence, collision with another object, or some catastrophic event." *Busbee v. Chrysler Corp.*, 240 Ga. App. 664, 666 (1999). "Defects

of quality, evidenced by internal deterioration or breakdown," ordinarily are insufficient. *See Vulcan Materials Co. v. Driltech, Inc.*, 251 Ga. 383, 385 (1983). Stradis has cited evidence that exposure to the eyewash carries some risk of infection that may lead to the loss of an eye. Though serious, nothing in the record suggests that such an infection would arise with the suddenness or violence that Georgia law requires. The court is persuaded that the exception does not apply to Stradis's claim, and thus Stradis's strict liability claim against Geri-Care is barred by the economic loss doctrine. Accordingly, the court will grant Geri-Care's motion for summary judgment as to Stradis's strict liability claim.

**c. Breach of Warranty**

The court's choice of law analysis, above, also resolves the merits of Stradis's breach of warranty claims. Under Georgia law, a plaintiff must have privity with the seller in order to recover under theories of breach of express warranty, implied warranty of merchantability, and fitness for a particular purpose where the plaintiff claims no personal injury. *Keaton v. A.B.C. Drug Co.*, 266 Ga. 385, 386 (1996); *Gowen v. Cady*, 189 Ga. App. 473, 476 (1988); *Cobb Cnty. Sch. Dist. v. MAT Factory, Inc.*, 215 Ga. App. 697, 702 (1994); Ga. Code Ann. §§ 11-2-313, 11-2-314, 11-2-315, 11-2-318. There is no dispute that Stradis and Geri-Care were not in contractual privity. Accordingly, the court will grant Geri-Care's motion for summary judgment as to Stradis's breach of warranty claims.[16]

**CONCLUSION**

For the reasons stated above, the court will: (1) as to KeraLink's motion for summary judgment against Stradis, grant as to strict liability, grant as to breach of express warranty, grant

[16] As none of Stradis's claims against Geri-Care for damages resulting from its purchase of the eyewash survive summary judgment other than contribution and indemnity, Geri-Care's related motion to exclude *in limine* certain damages claimed by Stradis is moot and will be denied.

as to breach of implied warranty of merchantability, and grant as to breach of implied warranty of fitness for a particular purpose; (2) as to KeraLink's motion for summary judgment against Geri-Care, grant as to strict liability and grant as to breach of implied warranty of merchantability; (3) as to Geri-Care's motion for summary judgment against Stradis, grant as to Stradis's claim for strict liability, and grant as to Stradis's breach of warranty claims; (4) as to Geri-Care's motion for summary judgment against KeraLink, grant as to KeraLink's breach of express warranty and deny as to KeraLink's claim for negligence; (5) as to Stradis's motion for summary judgment against KeraLink, deny as to all claims; (6) as to Stradis's motion for summary judgment against Geri-Care, grant as to contribution and indemnification and deny as to strict liability; (7) as to Stradis's motion for summary judgment against InSource, deny as to all claims; and (8) as to InSource's motion for summary judgment against Stradis, grant as to Stradis's claim for indemnification and contribution. The court will also deny Geri-Care's motion in limine and motion for order to show cause. The associated motions to seal will be granted.

A separate Order follows.

9/27/21
Date

/s/
Catherine C. Blake
United States District Judge